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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

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| SCOTT DENNISTON and his wife, DEBBIE DENNISTON,<br><br>Plaintiffs,<br><br>v.<br><br>ADVANCED BIONICS CORPORATION, a California Corporation, ADVANCED BIONICS, LLC, a Delaware Limited Liability Company, ASTRO SEAL CORPORATION, a California Corporation, and DOES 1 through 50 Inclusive,,<br><br>Defendants. | No.<br><br>**COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL FOR (1) NEGLIGENCE PER SE; (2) NEGLIGENCE PER SE; (3) STRICT LIABILITY; (4) NEGLIGENCE AND STRICT LIABILITY FOR FAILURE TO WARN; (5) NEGLIGENCE; (6) BREACH OF EXPRESS WARRANTIES; (7) BREACH OF IMPLIED WARRANTIES; (8) COMMON LAW FRAUD; (9) CA CONSUMERS LEGAL REMEDIES ACT; (10) CA CONSUMERS LEGAL REMEDIES ACT – INJUNCTIVE RELIEF; (11) CA UNFAIR UNCOMPETITION LAW; AND (12) KENTUCKY CONSUMER PROTECTION** |

Scott Denniston and wife Debbie Denniston hereby sue Defendants Advanced Bionics Corporation, Advanced Bionics, LLC, Astro Seal, Inc. and Does 1-50, for damages, and respectfully allege in support thereof as follows:

**PARTIES**

1. Plaintiff Scott Denniston was born October 1, 1949, making him fifty-nine (59) years old as of the filing of this lawsuit. At all times material to this lawsuit, Scott Denniston has resides in Campton, Kentucky. Scott Denniston was not born deaf but became deaf while working in mines during his adult life. He is now deaf and relies on both right and left side cochlear implants to hear.

2. Plaintiff Debbie Denniston is the wife of Scott Denniston, is over the age of 18, and resides with her husband in Campton, Kentucky.

3. Advanced Bionics Corporation is a California Corporation, with its principal place of business in Sylmar, California.

4. Advanced Bionics Corporation is the holding company for Advanced Bionics, LLC, a Delaware limited liability company, with its principal place of business in Sylmar, California. Defendants Advanced Bionics LLC and Advanced Bionics Corporation will collectively be referred to hereafter as "Advanced Bionics."

5. Advanced Bionics is in the business of manufacturing cochlear implant devices.

6. Astro Seal, Inc. is a California corporation, with its principal place of business in Riverside, California. Advanced Bionics hired Astro Seal to manufacture an important component part of its cochlear implant device known as a feedthru (or feed-through) assembly. Astro Seal manufactured and supplied the feedthru assemblies used in certain Advanced Bionics' cochlear implant devices. The feedthru is the part that conducts electrical signals from the hermetically (waterproof) sealed implanted part to the electrode array.

7. The true names and capacities of the defendants sued herein as Does 1 through 50, inclusive, are unknown to Plaintiffs, and are therefore sued under such fictitious names. Plaintiffs will amend this Complaint to allege the true names and capacities of Does 1 through 50, if and

when ascertained. Plaintiffs allege on information and belief that said fictitiously named defendants are in some manner responsible, in whole or in part, for the matters alleged herein.

## FACTUAL BACKGROUND

### I. COCHLEAR IMPLANTS

8. A cochlear implant is a Class III medical prosthesis designed to enable profoundly deaf persons to "hear" by directly stimulating auditory nerves leading to the brain by means of an electrode array strategically positioned in the cochlea of the inner ear.

9. Unlike hearing aids, cochlear implants do not amplify sound. Instead a miniature computer/sound processor, worn outside the body, selectively processes sound into coded signals. Such signals are transmitted by wireless electromagnetic conduction to an implantable cochlear stimulator (ICS) that is surgically implanted in the patient's body.

10. The ICS receives these coded signals and interprets them using its sophisticated microelectronic architecture to send specialized patterns of electrical current to the electrodes inserted inside of the cochlea. Multiple electrodes along the length of the electrode array emit electrical currents in the form of electrical stimulation pulses to the surrounding hearing nerve receptors based on scientific knowledge that different parts of the cochlear are sensitive to different sound frequencies. Nerve fibers then send this information to the brain for central processing, interpretation, and perception as sound.

11. Cochlear implant surgery requires general anesthesia and often involves a procedure called a mastoidectomy, in which an incision is cut and an indent is drilled into the skull to allow the attachment of the implant. Once the implant is attached, the electrode array is inserted in the delicate coiled cochlea of the inner ear by making a hole called a cochleonstomy and inserting the electrode array and pushing it through as gently as possible to avoid trauma to the inner surfaces. Post-surgery vertigo and nausea are common. Paralysis of the facial nerves is a rare but possible risk of surgery, as is tinnitus and damage to the vestibular system.

12. After surgery, initial programming of the external processor is not done until the incision has healed, which typically takes two to five weeks. At such initial stimulation and

programming, the individual electrodes are programmed at appropriate threshold and amplitude levels based on the patient's response to stimulation which is then used to create an electrode "map." Once all of the electrodes are mapped, the processor is turned on and the cochlear implant patient can "hear." This programming process continues to be fine-tuned at later appointments throughout the first year with the external processor eventually being programmed with multiple maps for different auditory environments.

13. In normal hearing, the cochlea is stimulated by hundreds of thousands of hair cells. The stimulation of the cochlea through implanted electrodes is very different. Thus a cochlear implant demands a long rehabilitation period in which the cochlear implant recipient's brain must learn how to decode and recognize sound.

14. The perception of sound by cochlear implant users is very different from normal hearing. Cochlear implant patients who have lost their hearing often describe the initial stimulation as hearing tinny "buzzes" and "whistles" that had no relation to what they remembered as sound and felt that they would never be able to comprehend.

15. Gradually through aural rehabilitation and listening experience, the brain may learn to decode sound. Over time, some cochlear implant recipients learn to distinguish sounds well enough so that they can talk on the telephone through the cochlear implant or listen to TV without closed-captioning.

16. When a defective cochlear implant is replaced, the electrode array may not be re-implanted in the same position in the cochlear, leading to different threshold and amplitude settings. As a result, rather than starting off by "hearing" at the comprehension level where the defective implant failed, a cochlear implant patient may have to go through a second aural rehabilitation before the replacement implant functions at the same level as the first implant did.

17. There is no guarantee that a replacement cochlear implant will ever function at the same level as the first. In some cases, due to cochlea scarring or nerve damage from explant surgery, different electrode positioning, or other causes, a cochlear implant patient may not function as well with the replacement implant.

18. Different cochlear implant manufacturers use different sound strategies. Thus when a defective implant is replaced with a new device by a different cochlear implant manufacturer, an entire new sound system needs to be learned.

19. Bilateral implantation, in which cochlear implants are surgically implanted in both ears, is increasingly becoming a desirable option for young children based on recent clinical research findings. The reasoning is that bilateral sound assures that sound is processed through both sides of the brain, which enables the brain to mature and to learn to process bilateral information during a period where maximum brain plasticity and linguistic development occurs.

## II. MR. DENNISTON'S EXPERIENCE WITH AN ADVANCED BIONICS' COCHLEAR IMPLANT

20. On or about February 11, 2005 Plaintiff Scott Denniston was implanted with an Advanced Bionics HiRes90k cochlear implant, serial number 302150, manufactured on January 16, 2005, behind his left ear at the University of Kentucky Medical Center in Lexington, Kentucky.

21. Prior to being implanted in February 2005 with the HiRes90k, Mr. Denniston lost his hearing while working in a mine. He had previously worn hearing aids to try and improve his deteriorating hearing, but eventually was diagnosed as completely deaf in his left year. Based on the recommendations of his doctors and audiologists, he chose an Advanced Bionics cochlear implant for implantation in his skull behind his left ear.

22. Astro Seal supplied Advanced Bionics with the feedthru component for the HiRes90k that was implanted during Mr. Denniston's surgery on February 11, 2005.

23. On or about June 2006, Mr. Denniston was advised via letter from Advanced Bionics that he had been implanted with a possibly defective component to his cochlear implant device. He was instructed of warning signs in which to pay attention to that could signify device failure.

24. On or about March 2008, after being diagnosed as completely deaf in his right ear, Mr. Denniston was implanted with a second Advanced Bionics cochlear implant behind his right ear.

25. On or about July 2008, while on vacation with his wife in Mackinaw City, Michigan, Mr. Denniston began to experience problems with his Advanced Bionics cochlear implant device implanted in February 2005.

26. On or about July 2008, Mr. Denniston began to experience severe head pain that upon information and belief was caused entirely by the failing Advanced Bionics cochlear implant inside his skull.

27. On or about July 2008 at the time he was experiencing head pain, Mr. Denniston's Advanced Bionics implant would also turn on and off without warning. Mr. Denniston heard both popping and crackling sounds inside of his head. Mr. Denniston was in pain as a result of the failing cochlear implant. The pains were sharp and caused distress to Mr. Denniston. Mr. Denniston's vacation was ruined as a result of the failed cochlear implant.

28. On or about July 15, 2008, Mr. Denniston and his wife traveled from Michigan to Kentucky for treatment of the cochlear implant device. Upon his return to Kentucky, Mr. Denniston's wife, Debbie Denniston, called Mr. Denniston's audiologist, Ms. Kari Mobley, for assistance. Ms. Mobley asked (through his wife) Mr. Denniston to come in for an appointment on a Friday. In order to travel from his home to the University of Kentucky Medical Center, Mr. Denniston was required to travel approximately 70 miles. Mr. Denniston could not talk on the phone after his left-ear cochlear implant failed, and he still cannot talk on the phone today.

29. At the initial consultation following the July 2008 trip to Michigan with Ms. Mobley, the power and/or volume was turned up in Mr. Denniston's implant. Ms. Mobley called Advanced Bionics and was told by Advanced Bionics to turn the power up on Mr. Denniston's implant. Mr. Denniston recalls the device working when he left the audiologist, but the device remained working for only approximately ten miles following his departure from the University of Kentucky Medical Center. Mr. Denniston was never advised there was device failure or that he had suffered any injury as of the date of this audiologist appointment.

30. On July 16, 2008, Mr. Denniston drove from his home to the University of Kentucky Medical Center in Lexington, Kentucky. By 8:00AM, Mr. Denniston was there waiting for Ms. Mobley to arrive for work. Ms. Mobely told Mr. Denniston when he arrived at her office